

2.0 RESPONSE

2.1 STATUS OF THE CLAIMS

Claims 1-46 and 49-55 were pending at the time of the Restriction Requirement.

Claims 16-46 and 49-55 have been withdrawn herein without prejudice and without disclaimer, as being drawn to non-elected inventions.

Claims 1-15 have been amended herein.

Claims 56-66 have been added herein.

Claims 1-15 and 56-66 are now pending in the application.

2.2 RESTRICTION

The Action subjected the present application to the following fifteen-way restriction:

Group 1 – Claims 1-15 drawn to methods of nuclear transfer.

Group 2 – Claims 16-33 drawn to methods of producing cloned animal embryos by transferring a segregated donor nucleus in the G1 stage of the cell cycle into an enucleated recipient cell.

Group 3 – Claims 34-46 drawn to methods of producing an embryonic cell line.

Group 4 – Claims 49-51 drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue, wherein the disease is a neurological disorder.

Group 5 – Claims 49-51 drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue, wherein the disease is diabetes.

Group 6 – Claim 49-51 drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue, wherein the disease is heart disease.

Group 7 – Claim 49-51 drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue wherein the disease is muscular dystrophy.

Group 8 – Claims 49-51, drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue, wherein the disease is various hereditary diseases.

Group 9 – Claims 49-51, drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue, wherein the disease is a specific cancer.

Group 10 – Claims 49-51 drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue wherein the disease is spinal cord injury.

Group 11 – Claims 49-51 drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue, wherein the disease is burns.

Group 12 – Claims 49-51 drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue wherein the disease is other afflictions.

Group 13 – Claim 53 drawn to a method of drug discovery or toxicology testing of drugs in vitro.

Group 14 – Claim 54 drawn to a method of xenotransplantation.

Group 15 – Claims 55-56 drawn to methods of gene therapy.

(Applicants note for the record that no claim 56 was pending, so Group 15 should have been drawn to a single claim, claim 55).

2.3 THE RESTRICTION IS IMPROPER

Page 3 of the action states “The inventions listed as Groups I-VII (*sic*) do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features.....”

Applicants respectfully traverse, and point out to the Office that during the PCT phase of prosecution *NO LACK OF UNITY OF INVENTION* was identified. Examination of novelty, inventive step, and industrial applicability was conducted on ALL pending claims, and original claims 1-56 of the PCT case were *all* found to be allowable in view of the prior art of record. The International Preliminary Examination Report did NOT consider that there was a lack of a unifying special technical feature. As such, Applicants believe that the restriction requirement in its entirety is improper, and respectfully requests that it be withdrawn.

2.4 THE RESTRICTION IS INCOMPLETE

According to MPEP §814, “the separate inventions should be identified by a grouping of the claims with a short description of the total extent of the invention claimed in each group, specifying the type or relationship of each group as by stating the group is drawn to a process, or to a subcombination, or to a product, etc., and should indicate the classification or separate status of each group, as for example, by class and subclass.” (Emphasis added)

Applicants note for the record that the present restriction does not list the classification of the allegedly distinct inventions by class and subclass, and as such, is incomplete as defined by Office practice guidelines. Applicants respectfully request, therefore, that any subsequent Action issued in the present case provide the omitted information.

2.5 THE RESTRICTION IS INACCURATE

Applicants also note for the record, that there was no claim 56 pending at the time of the requirement, and that claim 52 has not been identified to fall within any of the fifteen alleged restriction groups. However, Applicants have taken these errors into account when formulating their enclosed amendment and provisional restriction election without undue consequences to the continued prosecution of this case on the merits.

2.6 REQUEST FOR RECONSIDERATION OF THE RESTRICTION

In view of the clear and convincing evidence from the International Examining Authority that the present application does not lack unity of invention, pursuant to 37 C. F. R. § 1.143, Applicants respectfully request reconsideration and modification of the restriction requirement. In particular, Applicants believe that at the very least, the imposition of Restriction Groups 4-12 for the subject matter of only 3 claims represents a severe economic burden on Applicants, and presents hardship upon Applicants with respect not only to prosecution, allowance, and maintenance costs, but also greatly delays the issuance of patents directed to applicants' invention.

Setting aside for the moment the contravention of the Unity of Invention finding in the parent case, and comparing the present application to other recent U.S. utility applications in the

same art unit, Applicants believe that a more reasonable and less burdensome restriction requirement would, at the very worst, consider the subject matter of Claims 49 and 50 to be properly defined as a restriction group, and that the subject matter of Claims 51 and 52 be defined as a separate restriction group, with claim 51 to be generic, and a *species* election for the species of diseases to be treated as listed in claim 52.

2.7 APPLICANTS' PROPOSED RESTRICTION/ELECTION

In view of current Office practice, and mindful of the restriction/species election guidelines presently adopted by TC1600, Applicants respectfully request that the present 15-way Restriction Requirement be vacated and that the following more reasonable 7-way restriction/species election form the basis for initial consideration of the claimed inventions:

Group 1 – Claims 1-15 drawn to methods of nuclear transfer.

Group 2 – Claims 16-46 drawn to methods of producing cloned animal embryos and embryonic cell lines.

Group 3 – Claims 49-50 drawn to methods of therapeutic cloning.

Group 4 – Claims 51-52 drawn to methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue.

(If Group 4 invention is elected, as claim 51 is generic, Applicants are required to provisionally elect from among the following species: neurological disorder, diabetes, heart disease, muscular dystrophy, hereditary disease, cancer, spinal cord injury, burns, or other afflictions.)

Group 5 – Claim 53 drawn to a method of drug discovery or toxicology testing of drugs *in vitro*.

Group 6 – Claim 54 drawn to a method of xenotransplantation.

Group 7 – Claim 55 drawn to methods of gene therapy.

Applicants request that such a reasonable restriction/election be entered to reduce the economic burden of simultaneously prosecuting large numbers of applications, and to give consideration to the issues of patent term and examination burden on the Office.

Applicants respectfully request that the previous restriction be vacated, and that the proposed 7-way restriction/species election presented herein be adopted for subsequent prosecution on the merits.

2.8 PROVISIONAL ELECTION

Although disagreeing with the Office as to the issuance of a restriction requirement in the first place, especially in view of the unity of invention finding in the PCT phase of international prosecution of the related application, and particularly disagreeing with the Office as to the characterization of the subject matter of claims 49-51 as allegedly properly restrictable into 9 separate inventions, Applicants are nevertheless required to provisionally elect a group for initial examination. Pursuant to 37 C. F. R. § 1.111, and to that end, Applicants provisionally elect the Group I invention (claims 1-15) for examination. Newly added claims 56-66 are properly directed to the subject matter of the Group I restriction, and as such, are allowable for entry.

Applicants also note for the record, that should the Office accept Applicants' proposed 7-way restriction/species election, Applicants would elect the proposed Group I invention for initial examination without traverse.

2.9 SUPPORT FOR THE CLAIMS

Support for the pending claims can be found throughout the original claims, specification and figures as filed. It will be understood that no new matter is included within any of the newly-

submitted claims. Applicants authorize any additional fees necessitated by the presently added claims to be deducted from Applicants' Representatives' Deposit Account as noted above.

2.10 CHANGE OF ADDRESS FOR APPLICANTS' UNDERSIGNED REPRESENTATIVE

Applicants note for the record that representation of this matter has been transferred to the undersigned representative who relocated his practice from Williams, Morgan & Amerson (customer number 0023720) to Haynes and Boone, LLP (customer number 0027683) effective March 9, 2005. Authorization for the transfer of this matter to the new firm has been granted and the representative's new firm has submitted under separate cover a revocation of power of attorney, a new power of attorney, and a change of customer number/correspondence address to formalize this change of representative.

The new attorney docket number for this case is 36697.6, and Applicants appreciate the Examiner's so noting of this in subsequent communication with the undersigned representative.

Should the Office or the Examiner-in-Charge of this application have any questions, the Applicants' undersigned representative may be contacted at the following address:

**Mark D. Moore, Ph.D.
HAYNES AND BOONE, L.L.P.
901 Main Street, Suite 3100
Dallas, Texas 75202-3789
Telephone: 713/547-2040
Facsimile: 214/200-0853**

3.0 CONCLUSION

Applicants believe this to be a full, complete, and timely response to the outstanding restriction requirement. Should the Examiner have any questions, a telephone call to the undersigned Applicants' representative would be appreciated.

Respectfully submitted,



Mark D. Moore, Ph.D.
Registration No. 42,903

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HAYNES AND BOONE, LLP
901 Main Street, Suite 3100
Dallas, Texas 75202-3789
Telephone: 713-547-2040
Facsimile: 214 200-0853
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